

REMARKS

Claims 1, 2, 11 and 13-15 are amended to clarify the invention.

Dependent claim 17 is added.

Support for “an order entry processor for entering orders for administration of treatment to a patient” and generation of a message to alert a “user of said order entry processor” is found in Figure 1 units 102 and 112 and accompanying description and Application page 13 lines 3-5 (“At step 206, the method 200 initiates generation of a message 212 to alert a message recipient (e.g., a user of the client 102) of an identified potential change in use of the particular treatment”), for example, in the existing claims and other places. Support for “said message processor automatically and proactively initiating generation of said message in response to said user selecting said particular treatment for order” is similarly found in Figure 1 units 102 and 112 and accompanying description and Application page 13 lines 3-5, in the existing claims and other places. It is submitted no new material is added by this amendment.

I. Rejection of claims 1-14 under 35 U.S.C. 103(a)

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,583,758 - McIlroy in view of US Patent Application 2007/0214002 - Smith. These claims as amended are deemed patentable over the cited references. Note, the Rejection on page 3 appears to incorrectly state that claims 1, 3-11, 21 and 22 are Rejected, yet there are only 16 claims in the Application. Applicant assumes the Examiner means claims 1-14.

Amended claim 1 recites a “system for analyzing data comprising healthcare orders initiating treatment or services used in patient healthcare” comprising “a data processor for identifying a potential change in use of a particular treatment by, examining data representing a plurality of orders for treatment administration to a patient generated by healthcare clinicians over a particular time period and used in treating a plurality of patients, to identify a number of orders initiating application of a particular treatment to individual patients of said plurality of patients to address a particular medical condition; and determining at least one of (a) whether said number of orders exceeds a

predetermined threshold, and (b) whether a rate of change in said number of orders relative to a previously determined number of orders is significant to identify a potential change in use of said particular treatment; an order entry processor for entering orders for administration of treatment to a patient; and a message processor for automatically and proactively initiating generation of a message to alert a user of said order entry processor to permit review and potential modification of at least one order for said particular treatment corresponding to the identified potential change in use of said particular treatment in response to determining that at least one of (a) said number of orders exceeds a predetermined threshold, and (b) said rate of change in said number of orders relative to a previously determined number of orders is significant". McIlroy with Smith fails to show or suggest the claimed arrangement.

McIlroy with Smith fails to show or suggest "a data processor" for "determining at least one of (a) whether said **number of orders** exceeds a predetermined threshold, and (b) whether a rate of change in said **number of orders** relative to a previously determined number of orders is significant to identify a potential change in use of said particular treatment". McIlroy with Smith fails to show or suggest "initiating generation of a message to alert a user of said order entry processor to permit review and potential modification of at least one order for said particular treatment corresponding to the identified potential change in use of said particular treatment in response to determining that at least one of (a) said number of orders exceeds a predetermined threshold, and (b) said rate of change in said number of orders relative to a previously determined number of orders is significant".

Contrary to the Rejection statement on page 3 McIlroy in the Abstract, Figure 26 and column 18 lines 33-58 relied on does not show or suggest "examining data representing a plurality of orders for treatment administration to a patient generated by healthcare clinicians over a particular time period and used in treating a plurality of patients, to identify a **number of orders** initiating application of a particular treatment to individual patients of said plurality of patients to address a **particular medical condition**". Figures 26, 27 and 28 of McIlroy show reports that list usage of treatment guidelines ("the number of cases using the various guidelines 251", column 18 lines 40-41). Orders "for treatment administration to a patient" are NOT guidelines. McIlroy defines guidelines at col. 7, lines 45-53 (Guidelines) as:

Diagnosis-based guidelines provide a framework to reflect the critical factors in the clinical decision process usually leading to treatment, to define optimal resource allocation, and to outline key patient data. A guideline is not a fixed formula or cookbook, although it must be a definite, step by step algorithm that can be coded; rather, a guideline presents a disciplined framework or process to guide and assist the user, such as a health care provider, in identifying appropriate treatment.

An exemplary guideline is shown in McIlroy Figure 18 and comprises a treatment process involving diagnostic steps. Consequently the number of cases using treatment process guidelines is not, and does NOT suggest identifying "a number of orders initiating application of a particular treatment to individual patients of said plurality of patients to address a particular medical condition". Orders are for treatment administered to a patient and are analyzed by the system to provide treatment decision support to a physician using "an order entry processor for entering orders for administration of treatment to a patient" by "automatically and proactively initiating generation of a message to alert a user of said order entry processor to permit review and potential modification of at least one order for said particular treatment corresponding to the identified potential change in use of said particular treatment". The McIlroy analysis of treatment guidelines does not provide an analysis of orders and therefore fails to support or suggest or provide any enabling teaching to "alert a user of said order entry processor to permit review and potential modification of at least one order for said particular treatment".

McIlroy defines reports at col. 18, lines 16-25 (Reports) as:

Information management reports identify overall volume and patterns of care including diagnosis, therapeutic selection and resource use. From these reports, you can determine the level of effectiveness or impact related to each guideline use. You can also use the reports for quality measurement and planning by identifying where variations are occurring and how they are resolved at the initial guideline level. Reports may be selected by date in either clinician identification number or reviewer identification number or both.

25 They are sorted automatically by specialty area.

The patterns of care including diagnosis, therapeutic selection and resource use, concern treatment guidelines and does NOT suggest identifying "a number of orders initiating application of a particular treatment to individual patients of said plurality of patients to address a particular medical condition".

As recognized in the Rejection on page 3, McIlroy fails to show or suggest “determining at least one of (a) whether said **number of orders** exceeds a predetermined threshold, and (b) whether a rate of change in said **number of orders** relative to a previously determined number of orders is significant to identify a potential change in use of said particular treatment”. Smith in claims 17 and 25 and para. 0121 merely mentions comparing monitored parameters of a patient e.g. comparing vitals signs against a threshold (“the intervention guideline is configured to be indicative of a predetermined threshold being reached for **pre-specified variables** pertaining to the **chronic health related condition** of the patient”, Smith claim 25). Comparing a monitored parameter of a patient against a threshold does not suggest determining a “**number of orders**” for “administration of treatment to a patient” “exceeds a predetermined threshold”. Orders are NOT, and do not suggest, monitored patient parameters. A patient measured parameter e.g., blood pressure is merely measured data which does not suggest, an order for treatment that is administered to a patient.

A combination of McIlroy and Smith as suggested merely provides a system for reporting on usage of treatment guidelines and comparing patient monitored parameters against a threshold. Such a combination fails to show or suggest “determining at least one of (a) whether said **number of orders** exceeds a predetermined threshold, and (b) whether a rate of change in said **number of orders** relative to a previously determined number of orders is significant to identify a potential change in use of said particular treatment”. Consequently, withdrawal of the Rejection of claim 1 under 35 USC 103(a) is respectfully requested.

Amended dependent claim 2 is considered to be patentable based on its dependence on claim 1. Claim 2 is also considered patentable because McIlroy with Smith, neither discloses nor suggests “said message processor automatically and proactively initiating generation of said message in response to said user selecting said particular treatment for order and including an acquisition processor for acquiring data representing said plurality of orders used in treating said plurality of patients and for associating an individual order with at least one of (a) said particular medical condition, and (b) a set of medical conditions including said particular medical condition”. The Rejection states that a “plurality of orders” is represented by the diagnosis codes of McIlroy Figure 12a. Diagnosis codes concern diagnosis NOT treatment and do not suggest orders for treatment. Diagnosis is different to treatment to one of ordinary skill in the art and does not

reasonably suggest orders for treatment. Diagnosis occurs at a different point in the healthcare cycle and precedes treatment.

Claims 3-14 are considered to be patentable for reasons given in connection with claims 1 and 2 and because of the additional feature combinations they present.

II. Rejection of claims 15-16 under 35 U.S.C. 103(a)

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,740,800 - Hendrickson in view of US Patent Application 2007/0214002 - Smith. These claims as amended are deemed patentable over the cited references.

Amended claim 15 recites a “method for analyzing data comprising healthcare orders initiating treatment or services used in patient healthcare to identify a potential change in use of a particular treatment” comprising “examining data representing a plurality of orders for treatment administration to a patient generated by healthcare clinicians over a particular time period and used in treating a plurality of patients, to identify a number of orders initiating application of a particular treatment to individual patients of said plurality of patients to address a particular medical condition; and determining at least one of (a) whether said number of orders exceeds a predetermined threshold, and (b) whether a rate of change in said number of orders relative to a previously determined number of orders is statistically significant to identify a potential change in use of said particular treatment; and automatically and proactively initiating generation of a message to alert a user of an order entry processor for entering orders for administration of treatment to a patient to permit review and potential modification of at least one order for said particular treatment corresponding to the identified potential change in use of said particular treatment in response to determining that at least one of (a) said number of orders exceeds a predetermined threshold, and (b) said rate of change in said number of orders relative to a previously determined number of orders is significant”. These features are nowhere shown or suggested by Hendrickson with Smith.

Hendrickson with Smith fails to show or suggest “determining that at least one of (a) said **number of orders** exceeds a predetermined threshold, and (b) said **rate of change** in said **number of orders** relative to a previously

determined number of orders is significant". Hendrickson with Smith fails to show or suggest "automatically and proactively initiating generation of a message to alert a user of an order entry processor for entering orders for administration of treatment to a patient to permit review and potential modification of at least one order for said particular treatment corresponding to the identified potential change in use of said particular treatment".

Contrary to the Rejection statement on page 3 Hendrickson in Figures 2-4A, column 2 lines 10-56, column 4 line 5 to column 5 line 20 relied on does not show or suggest "examining data representing a plurality of orders for treatment administration to a patient generated by healthcare clinicians over a particular time period and used in treating a plurality of patients, to identify a number of orders initiating application of a particular treatment to individual patients of said plurality of patients to address a particular medical condition". Figures 2-4A of Hendrickson relied on are merely order entry screens enabling a user to place an order for a patient ("FIG. 2 is an example of a clinical pathway order selection display in the medical information system of FIG. 1; FIG. 3 is an example of a clinical pathway order set used in the medical information system of FIG. 1; and FIGS. 4A and 4B show a flow diagram of an example of the physician order selection process in accordance with the invention", Hendrickson column 2 line 66 to column 3 line 5). Further, Hendrickson in column 4 line 5 to column 5 line 20 relied on, merely discusses selection of orders and order sets and associating a selection with a point in a treatment cycle ("As indicated above, one or more physician order sets may be associated with some or all of the time intervals in the clinical pathway. Thus, for a clinical pathway representative of a specific disorder, different predefined order sets may be associated with day one, day two, day three, etc. or other suitable time intervals, of the clinical pathway", column 4 lines 55-59). Hendrickson fails to suggest or mention a "number of orders" at all.

As recognized in the Rejection on page 12, Hendrickson fails to show or suggest "determining at least one of (a) whether said number of orders exceeds a predetermined threshold, and (b) whether a rate of change in said number of orders relative to a previously determined number of orders is significant to identify a potential change in use of said particular treatment". Smith in claims 17 and 25 and para. 0121 merely mentions comparing monitored parameters of a patient e.g. comparing vitals signs against a threshold ("the intervention guideline is configured to be indicative of a predetermined threshold

being reached for **pre-specified variables** pertaining to the chronic health related condition of the patient”, Smith claim 25). Comparing a monitored parameter of a patient against a threshold does not suggest determining a “**number of orders**” for “administration of treatment to a patient” “exceeds a predetermined threshold”. Orders are NOT and do not suggest monitored patient parameters. A patient measured parameter e.g., blood pressure is merely measured data which does not suggest, an order for treatment that is administered to a patient.

A combination of Hendrickson and Smith as suggested merely provides a system for using a clinical pathway model in ordering treatment and comparing patient monitored parameters against a threshold. Such a combination nowhere shows or suggests “determining at least one of (a) whether said **number of orders** exceeds a predetermined threshold, and (b) whether a rate of change in said **number of orders** relative to a previously determined number of orders is significant to identify a potential change in use of said particular treatment”. Further, Hendrickson teaches an exclusively clinical pathway driven ordering system (“In a preferred embodiment, a **list of the clinical pathway order sets** associated with the selected clinical pathway is displayed on the display screen. The next order set is indicated on the list of clinical pathway order sets. Clinical pathway order sets that have been used for the patient may also be indicated on the list of clinical pathway order sets. The **user selects an order set from the list**. The selected order set, typically the next order set, is displayed, and the user enters desired orders”, column 2 lines 27-35). To the extent Hendrickson teaches selecting orders exclusively based on clinical pathway Hendrickson is teaching away from the claimed arrangement and from “automatically and proactively initiating generation of a message to alert a user of an order entry processor for entering orders for administration of treatment to a patient to permit review and potential modification of at least one order for said particular treatment corresponding to the identified potential change in use of said particular treatment”. Consequently, withdrawal of the Rejection of claim 15 under 35 USC 103(a) is respectfully requested.


Dependent claim 16 is considered to be patentable based on its dependence on claim 15. Claim 16 is also considered patentable because Hendrickson with Smith, neither discloses nor suggests “acquiring data representing said plurality of orders used in treating said plurality of patients and for associating an individual order with at least one of (a) said particular medical

condition, and (b) a set of medical conditions including said particular medical condition".

New dependent claim 17 is considered to be patentable based on its dependence on claim 15. Claim 17 is also considered patentable because Hendrickson with Smith, neither discloses nor suggests "said step of automatically and proactively initiating generation of a message to alert said user of said order entry processor to permit review and potential modification of said least one order occurs in response to determining a rate of change in said number of orders relative to a previously determined number of orders is significant".

In view of the above amendments and remarks, Applicants submit that the Application is in condition for allowance, and favorable reconsideration is requested.

Respectfully submitted,



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